

## **REMARKS**

This amendment is in reply to the non-final Office Action mailed October 5, 2006. Claims 11, 12 and 15-36 are pending. In the claim amendment, new claims 37 and 38 have been added. Upon entry of the amendments to the claims, claims 11, 12 and 15-38 will be pending and under consideration.

### **I. AMENDMENTS TO THE CLAIMS**

New claims 37 and 38 are supported, for example, by the specification from page 2, line 19, to page 3, line 2. The amendments to the claims are fully supported by the specification and claims as originally filed. No new matter is added with these amendments. Entry of the amendments to the claims is respectfully requested.

### **II. INTERVIEW WITH THE EXAMINER**

Applicants thank the Patent Office for the courtesy extended during a telephone interview on March 6, 2007, in which participants included Examiner Deborah K. Ware, Supervisor David Naff, Nikolaos C. George and Roger C. Rich. In the interview, the rejection of claims 11, 12 and 15-36 under 35 U.S.C. § 103(a) was discussed. The content of the remarks presented herein reflect the discussion that took place during the interview.

### **III. CLAIM REJECTION UNDER 35 U.S.C. § 103(a)**

Claims 11, 12 and 15-36 stand rejected under 35 U.S.C. § 103(a) as being obvious over Shaikenov *et al.*, WO 99/43314 (“Shaikenov *et al.*”) in view of Zhou *et al.*, 1993, *Phytochemistry* 34(1):249-52 (“Zhou *et al.*”). Applicants respectfully traverse the rejection.

Under the current legal standard, a combination of prior art references cannot render a claim obvious unless the Patent Office provides evidence that the combination of references meets a three-part test for *prima facie* obvious. First, the prior art reference or references must provide “motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant.” *See In re Kotzab*, 55 U.S.P.Q.2d 1313, 1316 (Fed. Cir. 2000). Second, the prior art references cited by the Patent Office must suggest to one of ordinary skill in the art that the invention would have a reasonable expectation of success. *See Noelle v. Lederman*, 69 U.S.P.Q.2d 1508, 1516 (Fed. Cir. 2004). Finally, the Patent Office must show that the prior art references, either alone or in combination, teach or

suggest each and every limitation of the rejected claims. *See Motorola, Inc. v. Interdigital Tech. Corp.*, 43 U.S.P.Q.2d 1481, 1490 (Fed. Cir. 1997).

Shaikenov *et al.* fails to teach or suggest methods of treating cancer that comprise administration of a composition comprising an extract of *Inula britannica* wherein the extract comprises 1-*O*-acetylbritannilactone and/or 1,6-*O-O*-diacetylbritannilactone. Rather, Shaikenov *et al.* describes substantially pure preparations of phosphosesquiterpenes — a class of compounds that does not include either 1-*O*-acetylbritannilactone or 1,6-*O-O*-diacetylbritannilactone — and their use in treating cancer. *See, e.g.*, Abstract, line 1; page 3, lines 13-14; and page 40, claim 1, Shaikenov *et al.*

Moreover, Shaikenov *et al.* fails to teach or suggest that extracts of any plant it lists, let alone an extract of *Inula Britannica*, can be used in treating cancer. Rather, Shaikenov *et al.* merely identifies over twenty different genera/species of plants it states are useful for isolating sesquiterpenes. However, according to Shaikenov *et al.*, the isolated sesquiterpenes must be processed via *in vitro* or *in vivo* phosphorylation reactions such that they constitute substantially pure preparations of phosphosesquiterpenes. *See, e.g.*, page 21, lines 15-24, Shaikenov *et al.* With respect to *Inula Britannica*, it is only one of the listed sources. In particular, Shaikenov *et al.* states: “[t]he sesquiterpene lactone inuchinenolide C can be extracted from the whole plant of *Inula britannica* Var. *chinensis* as described by Ito, K. and Iida, T., (1981), *Phytochemistry*, 20(2):271-274.” *See* page 19, lines 18-20, Shaikenov *et al.* According to Shaikenov *et al.*, sesquiterpenes require activation by phosphorylation prior to exhibiting anti-cancer properties. *See* page 20, lines 19-21, Shaikenov *et al.*

Zhou *et al.* fails to cure the deficiencies of Shaikenov *et al.* Zhou *et al.* merely discloses that 1-*O*-acetylbritannilactone and 1,6-*O-O*-diacetylbritannilactone are both present in flowers of the *chinensis* variety of *Inula britannica*. *See* page 249, Zhou *et al.* The reference provides no teaching or suggestion that these or any compounds present in *Inula britannica* might be used for treating cancer. In any event, as explained above, Shaikenov *et al.* teaches that once a substantially pure preparation of a sesquiterpene is obtained, it is to be phosphorylated and that preparations of the resulting phosphosesquiterpenes are to be administered for treatment of cancer. *See, e.g.*, page 23, line 13, to page 25, line 26, Shaikenov *et al.* Thus, 1-*O*-acetylbritannilactone and 1,6-*O-O*-diacetylbritannilactone, which do not constitute phosphosesquiterpenes, are not included among those Shaikenov *et al.* teaches for administration for treatment of cancer. Further, 1-*O*-acetylbritannilactone and

1,6-*O-O*-diacetylbritannilactone would also fail to be included along with the phosphosquiterpenes of Shaikenov *et al.* because if they are phosphorylated then such compounds are no longer the compounds recited in the instant claims.

For these reasons, there is no teaching or suggestion in Zhou *et al.* or Shaikenov *et al.*, either alone or in combination, for a method comprising administering a composition comprising an extract of *Inula Britannica*, wherein the extract comprises 1-*O*-acetylbritannilactone or 1,6-*O-O*-diacetylbritannilactone for treating cancer.

Accordingly, it respectfully requested that the rejection of claims 11, 12 and 15-36 under 35 U.S.C. § 103(a) be withdrawn.

#### IV. DOUBLE PATENTING

Claims 11, 12 and 15-36 stand rejected under the judicially created doctrine of obviousness-type double patenting over U.S. Patent No. 6,627,623.

Applicants respectfully request that this rejection be held in abeyance until the allowable subject matter is determined at which point Applicants will consider filing a terminal disclaimer over U.S. Patent No. 6,627,623 or taking other appropriate action to overcome the rejection.

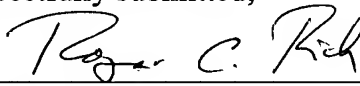
#### CONCLUSION

Entry of the foregoing amendments and remarks into the file of the application is respectfully requested.

No fees, other than that for the enclosed Petition for Extension of Time, are believed to be due with this response. However, the Commissioner is authorized to charge all required fees, or credit any overpayment, to Jones Day Deposit Account No. 50-3013 (referencing 517019-999019).

Date: April 5, 2007

Respectfully submitted,

  
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1,6-*O-O*-diacetylbritannilactone would also fail to be included along with the phosphosquiterpenes of Shaikenov *et al.* because if they are phosphorylated then such compounds are no longer the compounds recited in the instant claims.

For these reasons, there is no teaching or suggestion in Zhou *et al.* or Shaikenov *et al.*, either alone or in combination, for a method comprising administering a composition comprising an extract of *Inula Britannica*, wherein the extract comprises 1-*O*-acetylbritannilactone or 1,6-*O-O*-diacetylbritannilactone for treating cancer.

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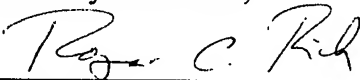
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